DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#14

Re: Albunex®
Docket No. 94E-0360

FEB 24 1995

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SPECIAL PROGRAMS OFFICE
DAC FOR PATENTS

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,844,882, filed by Molecular Biosystems, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Albunex®, the medical device claimed by the patent.

The total length of the review period for Albunex® is 2,397 days. Of this time, 975 days occurred during the testing phase and 1,422 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: January 14, 1988.

   The applicant claims that the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on August 18, 1987. However, FDA records indicate that the IDE was conditionally approved on January 14, 1988, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: September 14, 1990.

   The applicant claims September 11, 1990 as the date the Premarket Approval Application (PMA) for Albunex® (PMA P900059) was initially submitted. However, FDA records indicate that the PMA was submitted on September 14, 1990.

3. The date the application was approved: August 5, 1994.

   FDA has verified the applicant's claim that PMA P900059 was approved on August 5, 1994.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Allen B. Duncan

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Freddie K. Park
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